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(54) AN IMPLANT

IMPLANTAT

IMPLANT

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Description

TECHNICAL FIELD

[0001] The present invention relates to the field of medical technology and more specifically to the field of implantology, and relates to implants made of a porous, non-toxic material having a total open porosity exceeding 5 % by volume but not exceeding 80 % by volume within at least a portion of the implant, wherein it has communicating micropores having a size of not larger than 10 µm, said communicating micropores making up not more than 10 % of the total pore volume in said at least one portion of the implant; at least 5 % of at least one section of the surface of the implant is covered by substantially evenly distributed pores having a pore size exceeding 50 µm; and the implant contains bone ingrowth-promoting agents added to the implant through carriers, which completely or partially fill the micropores as well as the pores in the surface layer of the implant.

BACKGROUND ART

[0002] When implant materials are used and are subjected to a substantial mechanical load, a high strength is the primary requirement. This is achieved by using essentially conventional construction materials - e.g. stainless steel, cobalt-chromium alloys, titanium and titanium-alloys, various ceramic materials and polymers. In order to fix implants, it is common practice to utilize a topographical surface or pores. In this connection special requirements as to holding and bone ingrowth must be met.

[0003] WO 92/21302, published 22 July 1993, relates to an implant made of a porous non-toxic material with a total open porosity larger than 5 percent by volume but not larger than 80 percent by volume within at least a portion of the implant. The implant is characterized in that: communicating pores with a pore size within the interval of 0.1-10 µm occupy 10-80 percent of the total pore volume in said at least one portion of the implant; pores with a pore size within the interval of 10-50 µm occupy not more than 5 % of the total pore volume in said at least one portion of the implant; and 5-40 % of at least one portion of the surface of the implant is covered by mainly evenly distributed pores having a pore size within the interval of 50-500 µm.

[0004] This specific and complex pore size distribution can be utilised to accommodate bone in growth-promoting agents and to provide a satisfactory bone ingrowth in large pores.

BRIEF DISCLOSURE OF THE INVENTION

[0005] The object of the present invention is to provide an improve implant as compared to the implant according to said WO 92/21302. The present invention relates more specifically to substantially limiting the porosity of micropores by adding bone ingrowth-promoting agents through carriers, which completely or partially fill micropores as well as pores or cavities in the surface layer, which makes the need of a large available surface less important. Thus, another object of the invention is to improve the bone ingrowth and the healing not only by creating geometrical opportunities for a satisfactory ingrowth but also by allowing a time control of the bone ingrowth, through different concentrations and release of active agents.

[0006] Generally, the purpose of the invention is to provide implants having the following characteristics: high strength, excellent biocompatibility by using bone ingrowth-promoting agents deposited in pores or in surface areas for time controlled bone ingrowth in order to achieve an improved reproduceable holding of the implant.

[0007] These and other objects of the invention can be achieved therein that the micropores make up not more than 5% by volume of the implant.

[0008] The term pore size is defined, as far as pores having pore sizes smaller than or equal to 50 µm are concerned, as sizes calculated by means of conventional Hg-porosimetry, the relation between the pressure and the pore diameter (2r) being obtained through the expression:

$$p = \frac{2 s \cos F}{r}$$, in which:

- p = the pressure
- s = the surface tension of Hg for a certain temperature; and
- F = the miniscus angle (marginal angle; referens see L C Ritter and R L Drake, Ind. Eng. Chem. 17 782 (1945))

[0009] Pore sizes exceeding 50 µm are defined as sizes obtained through an optical measurement in a light microscope on a cross section of the specimens in a section made at a depth of 0.1 µm and in a section perpendicular to the surface of the specimen, respectively.

[0010] The larger pores preferably are limited to, i.e. exist essentially only in the surface layer, more particularly are limited to a surface layer having a thickness of 3 mm, preferably 2 mm and suitably 0.3 mm. If for the rest the porosity is limited to a microporosity, i.e. to pores not larger than 10 µm in diameter and having a total volume of micropores of not more than 10 %, a high strength can be maintained.

[0011] In the pores one or several of those agents, which include bone-promoting agents, agents for bone growth or bone in-growth, are deposited before the implantation, which agents can be included in a carrier, which can be made of a polymer, a hydrogel or the like.

Due to the fact that the pores can be completely filled with the carrier and the included active agents, which both of them will successively be released, pores will gradually be available for bone ingrowth. In this way various profiles for the bone ingrowth can be achieved by means of suitable concentration levels and distributions of active agents. Also, the release rate can be controlled by selecting carriers having different degrees of solubility. Different carriers can be used in different layers and/or in different parts of the implant in order to obtain an optimal ingrowth, e.g. a fast initial ingrowth (increased short-time release) designed to provide a quick holding and subsequently a slower ingrowth designed to provide a denser and stronger bone tissue.

[0012] Additional aspects and characteristic features of the present invention are set forth in the accompanying claims.

Claims

1. An implant made of a porous non-toxic material having a total open porosity exceeding 5 % by volume but not exceeding 80 % by volume within at least one portion of the implant;
wherein it has communicating micropores having a size of not larger than 10 µm, said communicating micropores making up not more than 10 % of the total pore volume in said at least one portion of the implant; at least 5 % of at least one section of the surface of the implant is covered by substantially evenly distributed pores having a pore size exceeding 50 µm; and the implant contains bone ingrowth-promoting agents added to the implant through carriers, which completely or partially fill the micropores as well as the pores in the surface layer of the implant, **characterized** in that the micropores make up not more than 5 % by volume of the implant.

2. An implant according to claim 1, **characterized** in that the size of the micropores is less than 5 µm and preferably less than 2 µm.

3. An implant according to any of claims 1-2, **characterized** in that the surface/surface layer within said at least one section of the implant is covered by pores (cavities) having a diameter size in the range 50-500 µm.

4. An implant according to any of claims 1-3, **characterized** in that the main portion of the large pores in the surface layer have a diameter size within the range 75-400 µm, preferably within the range 100-300 µm and suitably within the range 150-250 µm.

5. An implant according to any of claims 1-4, **characterized** in that the large pores (cavities) exist in a surface layer, which has a thickness of 3 mm, preferably 2 mm and suitably 0.3 mm.

6. An implant according to any of claims 1-5, **characterized** in that said at least one portion of the implant mainly consists of one or more materials, which are selected those materials which comprise from calcium phosphate materials, titanium, cobalt-chromium-alloys, stainless steels, silicon nitride and other types of cerams, and polymers.

7. An implant according to any of claims 1-6, **characterized** in that pores or surface areas of the implant surface or parts thereof contain deposited substances having desirable medical and/or biological functions.

8. An implant according to any of claims 1-7, **characterized** in that the deposited substance is made up of one or more bone ingrowth factors, preferably one or more of the substances IGF, PDGF, BMP and TGF.

9. An implant according to any of claims 1-7, **characterized** in that the deposited substance consists up of one or more antibiotics.

10. An implant according to any of claims 1-7, **characterized** in that the deposited substance consists of Ca-compounds of phosphate-type or fluorides.

11. An implant according to any of claims 1-7, **characterized** in that hyaluronic acid is deposited in the pores.

12. An implant according to any of claims 1-11, **characterized** in that the deposited substances are included separately or in combination, freely or in a gel and/or a polymer carrier.

13. An implant according to any of claims 1-12, **characterized** in that the deposition of substances is differentiated to various zones in order to control the growth rate and the bone tissue quality.

Patentansprüche

1. Implantat aus einem porösen nicht toxischen Material mit einer offenen Gesamtporosität von mehr als 5 Vol.-% aber von höchstens 80 Vol.-% in mindestens einem Teil des Implantats, wobei:
es kommunizierende Mikroporen mit einer Größe von höchstens 10 µm aufweist, und die kommunizierenden Mikroporen nicht mehr als 10 % des gesamten Porenvolumens in mindestens einem Teil des Implantats bilden; mindestens 5 % mindestens eines Abschnitts der Oberfläche des Implants mit im wesentlichen regelmäßig verteilten Poren, die eine Porengröße von mehr als 50 µm aufweisen, bedeckt ist und das Implantat Wirkstoffe enthält, die das Einwachsen des Knochens fördern, die dem

Implantat über Trägersubstanzen zugesetzt sind, welche die Mikroporen und die Poren in der Oberflächenschicht des Implantats vollständig oder teilweise ausfüllen, dadurch gekennzeichnet, daß die Mikroporen nicht mehr als 5 % des Implantatvolumens bilden.

2. Implantat nach Anspruch 1, dadurch gekennzeichnet, daß die Größe der Mikroporen unter 5 µm liegt, bevorzugt unter 2 µm.

3. Implantat nach Ansprüchen 1 bis 2, dadurch gekennzeichnet, daß die Oberfläche/Oberflächenschicht in mindestens einem Abschnitt des Implantats mit Poren (Hohlräumen) bedeckt ist, die einen Durchmesser im Bereich von 50 bis 500 µm aufweisen.

4. Implantat nach Ansprüchen 1 bis 3, dadurch gekennzeichnet, daß der Hauptanteil der großen Poren in der Oberflächenschicht einen Durchmesser im Bereich von 75 bis 400 µm, bevorzugt im Bereich von 100 bis 300 µm und geeigneterweise im Bereich von 150 bis 250 µm aufweist.

5. Implantat nach Ansprüchen 1 bis 4, dadurch gekennzeichnet, daß die großen Poren (Hohlräume) in einer Oberflächenschicht liegen, die eine Dicke von 3 mm, bevorzugt von 2 mm und geeigneterweise von 0,3 mm aufweist.

6. Implantat nach Ansprüchen 1 bis 5, dadurch gekennzeichnet, daß mindestens ein Teil des Implantats hauptsächlich aus einem oder mehreren Materialien besteht, die aus solchen Materialien ausgewählt sind, welche Calciumphosphatmaterialien, Titan, Kobalt, Chromlegierungen, rostfreien Stahl, Siliziumnitrid und andere Arten von Keramik oder Polymeren umfassen.

7. Implantat nach Ansprüchen 1 bis 6, dadurch gekennzeichnet, daß die Poren oder Oberflächenbereiche der Implantatoberfläche oder Teile davon eingelagerte Substanzen enthalten, die erwünschte medizinische und/oder biologische Funktionen haben.

8. Implantat nach Ansprüchen 1 bis 7, dadurch gekennzeichnet, daß die eingelagerte Substanz aus einem oder mehreren Knocheneinwuchsfaktoren bevorzugt aus einer oder mehreren der Substanzen IGF, PDGF, BMP und TGF besteht.

9. Implantat nach Ansprüchen 1 bis 7, dadurch gekennzeichnet, daß die eingelagerte Substanz aus einem oder mehreren Antibiotika besteht.

10. Implantat nach Ansprüchen 1 bis 7, dadurch gekennzeichnet, daß die eingelagerte Substanz aus Calciumverbindungen des Phosphat-Typs oder Fluoriden besteht.

11. Implantat nach Ansprüchen 1 bis 7, dadurch gekennzeichnet, daß Hyaluronsäure in den Poren eingelagert ist.

12. Implantat nach Ansprüchen 1 bis 11, dadurch gekennzeichnet, daß die eingelagerten Substanzen einzeln oder in Kombination, frei vorliegend oder in einem Gel und/oder einer polymeren Trägersubstanz enthalten sind.

13. Implantat nach Ansprüchen 1 bis 12, dadurch gekennzeichnet, daß die Einlagerung der Substanzen sich in verschiedenen Bereichen unterscheidet um die Wachstumsrate und die Qualität des Knochengewebes zu steuern.

Revendications

1. Implant constitué d'un matériau poreux non-toxique ayant une porosité ouverte totale dépassant 5 % en volume mais ne dépassant pas 80 % en volume dans au moins une partie de l'implant,
dans lequel il existe des micropores communicants ayant une dimension pas plus grande que 10 µm, lesdits micropores communicants ne constituant pas plus de 10 % du volume total de pores dans ladite au moins une partie de l'implant ; au moins 5 % d'au moins un tronçon de la surface de l'implant sont recouverts par des pores répartis de manière sensiblement régulière ayant une dimension de pore dépassant 50 µm ; et l'implant contient des agents favorisant la croissance osseuse interne ajoutés à l'implant par l'intermédiaire de porteurs, qui remplissent entièrement ou partiellement les micropores ainsi que les pores de la couche superficielle de l'implant, caractérisé en ce que les micropores ne constituent pas plus de 5 % en volume de l'implant.

2. Implant selon la revendication 1, caractérisé en ce que la dimension des micropores est plus petite que 5 µm et de préférence plus petite que 2 µm.

3. Implant selon la revendication 1 ou 2, caractérisé en ce que la surface/couche superficielle dudit au moins un tronçon de l'implant est recouverte par des pores (cavités) ayant une dimension diamétrale située dans la plage allant de 50 à 500 µm.

4. Implant selon l'une quelconque des revendications 1 à 3, caractérisé en ce que la partie principale des grands pores de la couche superficielle a une dimension diamétrale située dans la plage allant de 75 à 400 µm, de préférence dans la plage allant de

100 à 300 µm et de manière adaptée dans la plage allant de 150 à 250 µm.

5. Implant selon l'une quelconque des revendications 1 à 4, caractérisé en ce que les grands pores (cavités) existent dans une couche superficielle, qui a une épaisseur de 3 mm, de préférence 2 mm et de manière adaptée 0,3 mm.

6. Implant selon l'une quelconque des revendications 1 à 5, caractérisé en ce que ladite au moins une partie de l'implant est constituée principalement d'un ou plusieurs matériaux, qui sont sélectionnés parmi les matériaux qui comportent des matériaux de phosphate de calcium, du titane, des alliages de cobalt et de chrome, des aciers inoxydables, du nitrure de silicium et d'autres types de céramiques, et des polymères.

7. Implant selon l'une quelconque des revendications 1 à 6, caractérisé en ce que les pores ou les surfaces superficielles de la surface d'implant ou des parties de celui-ci contiennent des substances déposées ayant des fonctions médicales et/ou biologiques souhaitables.

8. Implant selon l'une quelconque des revendications 1 à 7, caractérisé en ce que la substance déposée est constituée d'un ou plusieurs facteurs de croissance osseuse interne, de préférence une ou plusieurs des substances IGF, PDGF, BMP et TGF.

9. Implant selon l'une quelconque des revendications 1 à 7, caractérisé en ce que la substance déposée est constituée d'un ou plusieurs antibiotiques.

10. Implant selon l'une quelconque des revendications 1 à 7, caractérisé en ce que la substance déposée est constituée de composés de Ca du type phosphate ou de fluorures.

11. Implant selon l'une quelconque des revendications 1 à 7, caractérisé en ce qu'un acide hyaluronique est déposé dans les pores.

12. Implant selon l'une quelconque des revendications 1 à 11, caractérisé en ce que les substances déposées sont incluses de manière séparée ou en combinaison, librement ou dans un porteur de gel et/ou de polymère.

13. Implant selon l'une quelconque des revendications 1 à 12, caractérisé en ce que le dépôt de substances est différencié sur diverses zones afin de commander la vitesse de croissance et la qualité du tissu osseux.